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09/607,179	06/29/2000	Yuan Chang	45185-CA/JPW/SHS	1263

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EXAMINER

DAVIS, KATHARINE F

ART UNIT PAPER NUMBER

1636

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11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/607,179

Applicant(s)

CHANG ET AL.

Examiner

Katharine F. Davis

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1636

DETAILED ACTION

This Office Action is in response to the Amendment filed on May 28, 2002. Claims 43 and 49 are cancelled and new claims 50 and 51 are added which correspond to cancelled claims 43 and 49. Claims 50 and 51 are pending in the instant application.

All of the objections to the specification have been withdrawn in view of the amendments to the specification (and entry of substitute sequence listing) presented in the Amendment filed on May 28, 2002. The objection to claim 43, the rejection of claim 43 under 35 U.S.C. 112, first paragraph (enablement) and the rejection of claims 43 and 49 under 35 U.S.C. 112, second paragraph have all been withdrawn in view of the amendments to the claims and the remarks presented by the applicants in the Amendment filed on May 28, 2002.

Information Disclosure Statement

The document by Saiag *et al.* (Ann Der Ven 122:551-557 1995) has been considered by the Examiner and cited on the attached PTO-892 form based on the English translation of the original French document submitted as Exhibit B with the IDS filed on May 28, 2002.

Drawings

The formal drawings filed on May 28, 2002 have been approved by the draftsman.

Art Unit: 1636

Specification

An amendment was made to page 101, lines 5-32 of the instant specification by the Amendment filed on May 28, 2002 however it is not clear what text was actually changed because there are no brackets or underlining indicated in the marked-up version attached as Exhibit H to the Amendment.

It is noted that Experiment 8 is described on page 111 of the instant specification and Experiment 10 on page 112. It is unclear if this is a numbering error or if there is information missing (experiment 9).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50 and 51 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is based on the Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 50 is drawn to an isolated peptide encoded by a nucleic acid which is at least 30 nucleotides in length and has a nucleotide sequence which uniquely defines a herpes virus associated with Kaposi's sarcoma,

Art Unit: 1636

which herpes virus is present in and recoverable from the HBL-6 cell line (ATTC Accession No. CRL 11762). Claim 51 is drawn to a composition comprising the peptide of claim 50 and a carrier. These are genus claims encompassing any 30 nucleotide sequence (encoding any isolated peptide) of the entire genome of a herpes virus associated with Kaposi's sarcoma. Although the instant specification refers to many sequences of a herpes virus associated with Kaposi's sarcoma (for example: SEQ ID NO:1 page 19, ORF'S on pages 20-21, KS330BAM and KS627BAM, page 95), there are no examples of any specific 30 nucleotide sequence. The disclosure of many sequences of a herpes virus associated with Kaposi's sarcoma is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision the complete structure of any 30 nucleotide sequence based on the disclosed sequences. Additionally, there is no description of a representative number of species by partial structure and a function which correlates with structure as there is no disclosure of the specific 30 nucleotide sequence(s) which would encode the claimed isolated peptide(s).

Applicants' arguments presented on pages 11-13 of the Amendment filed on May 28, 2002 have been carefully considered but have not been found to be persuasive. Applicants maintain that the claimed invention is drawn to an isolated peptide encoded by a nucleic acid which is **at least** 30 nucleotides in length and point out the many amino acid sequences translated from complete ORFs shown in Figure 12 are specific KSHV polypeptides. Applicants further assert each of these peptides is encoded by a nucleic acid of at least 30 nucleotides in length. Applicants stress that no peptide encoded by a 30-nucleotide-long nucleic acid need be separately listed in order to satisfy the written description requirement and that there already

Art Unit: 1636

exists a vast array of species of the claimed peptide, for example SEQ ID NO:1, shown in Figure 3A.

According to the invention, any 30 nucleotide sequence of any ORF shown in Figure 12 and/or any 30 nucleotide sequence of SEQ ID NO:1 can encode the claimed peptide. The instant claims are specifically limited to those nucleotide sequences unique to herpes viruses that are associated with Kaposi's sarcoma, even more particularly limited to a herpes virus sequence present in and recoverable from the HBL-6 cell line. What is unique about the HBL-6 herpes viral strains as compared to other strains of herpes virus associated with Kaposi's sarcoma? Viruses are present within a host or a cell line such as HBL-6 as a heterogenous population. It is entirely possible that any randomly selected 30 nucleotide sequence will not be unique to all of the virus present. Without any examples of the specific 30 nucleotide sequence (structure) which encodes the claimed isolated peptide one of skill in the art would not be able to discern from the genus of herpes viruses which sequences would encode the claimed isolated peptide unique to Kaposi's sarcoma. Additionally, based on the language of claim 50 which states that the claimed nucleotide sequence uniquely defines a herpes virus associated with Kaposi's sarcoma it can reasonably be presumed that there are specific requirements for the claimed peptide to be absolutely unique to those herpes viruses only associated with Kaposi's sarcoma. Without any information regarding specific sequence structure or any descriptions of structure/function relationship for the 30 nucleotide sequence one of skill in the art would not be able to determine that these sequences are absolutely unique to those herpes viruses associated with Kaposi's sarcoma especially since the instant specification discloses at page 20, lines 12-23, that DNA of the invention (SEQ ID NO:1) can also be associated with many types of lymphoproliferative

Art Unit: 1636

disorders in addition to association with Kaposi's sarcoma. For example, if any 30 nucleotide portion of SEQ ID NO:1 can encode the claimed peptide, how would one of skill in the art discern that the claimed peptide does not also define a herpes virus associated with any of the lymphoproliferative disorders listed on page 20?

Applicants' further point out that under MPEP 2163, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by disclosure of relevant, identifying characteristics and that in the case of biomolecules relevant identifying characteristics include sequences. Satisfactory disclosure of a representative number depends on whether one of ordinary skill in the art would recognize that the applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. Applicants thus assert that clearly one of ordinary skill in the art would recognize that disclosure in the specification of a plurality of sequences at least 30 nucleotides in length constitutes possession of the claimed peptide.

However, applicants have not disclosed nucleotide sequences encoding the claimed peptide instead applicants have disclosed sequences from which the 30 nucleotide sequence encoding the claimed peptide can be selected. SEQ ID NO:1 alone is 20,710 nucleotides in length and may also be associated with disorders other than Kaposi's sarcoma. One of skill in the art would not be able to identify the claimed nucleotide sequence from 20,710 nucleotides which uniquely defines a herpes virus associated with Kaposi's sarcoma.

Therefore, the instant specification does not describe the claimed isolated peptide(s) and/or sequence(s) which uniquely define a herpes virus associated with Kaposi's sarcoma in such full, clear, concise and exact terms so as to indicate that applicant had possession of this

Art Unit: 1636

isolated peptide(s) and/or sequence(s) at the time of filing of the instant application. Therefore, for both the reasons above and the reasons made of record in the previous Office Action mailed on November 23, 2001, the rejection of claims 50 and 51 under 35 U.S.C. 112, first paragraph (written description) is maintained.

Conclusion

Claims 50 and 51 are rejected. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are

Application/Control Number: 09/607,179

Page 8

Art Unit: 1636


(703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or any inquiry concerning the formalities of this application

should be directed to Patent Analyst Tracey Johnson whose telephone number is (703) 305-2982.

Katharine F. Davis

August 9, 2002



JAMES KETTER
PRIMARY EXAMINER